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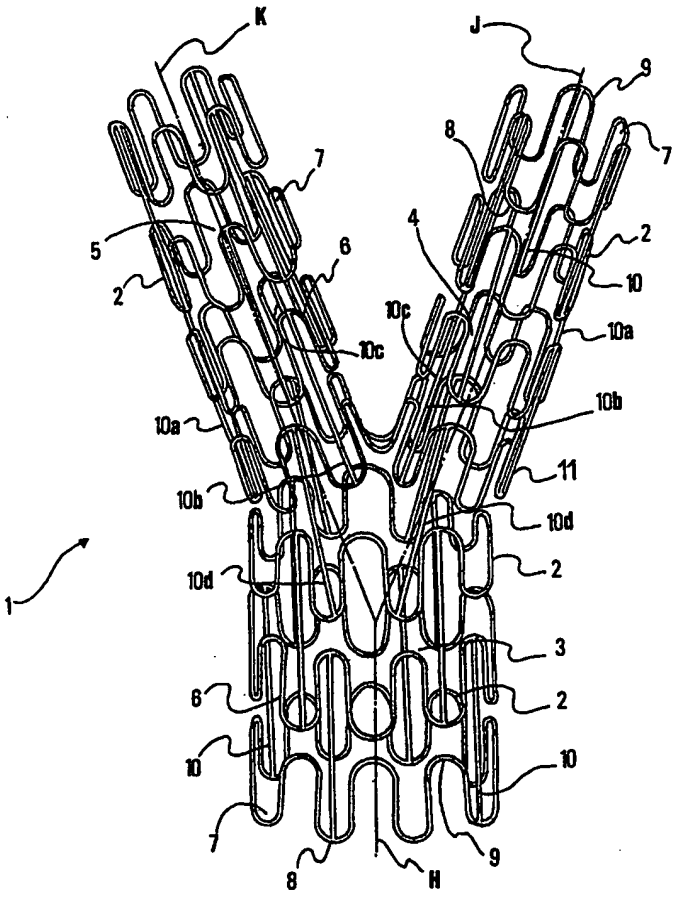
(54) Title: EXPANDABLE BIFURCATED STENT

(57) Abstract

Endovascular support device (1), used in particular in angioplasty, structurally strong and feasible to different forms of vessels bifurcations affected by stenosis, without interfering with the vessel flow and without leaving the vessels walls uncovered and comprising a proximal side–branch (3), a first distal side–branch (4) and a second distal side–branch (5), placed in a substantially Y–shaped configuration each one of them comprising a line of tubular segments radially expandable having a wire–like element (6) conformed in extensible turns (7) and laying on a substantially cylindrical surface and a linking segment (11) between said side–branches (3, 4, 5) having at least one wire–like element (6') conformed in successive extensible turns (7) and laying on a two–lobe (12, 13) surface, said proximal side–branch (3) and said first and second distal side–branch (4, 5) being fixed to the linking segment (11).



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EXPANDABLE BIFURCATED STENT

DESCRIPTION

The present invention relates to an endovascular support device, for example of the type intended to be delivered by percutaneous angioplasty.

In particular, said endovascular support device, referred to hereinafter more conveniently as a stent, comprises a plurality of tubular segments radially expandable and in mutual queuing, having each at least one wire-like element conformed in successive extensible turns and laying on a substantially cylindrical surface. Each tubular segment is fixed to the adjacent segments by connection elements.

The above specified stents are well known and are nowadays largely used in advanced angioplasty and in particular in the field of coronary, carotid and peripheral vessels angioplasty, for the treatment of stenosis, restenosis and similar affecting the above mentioned vascular districts.

Said stents are delivered by a specialist usually by percutaneous angioplasty, passing through a large peripheral vessel such as, for example, the femoral artery.

A guidewire or catheter is inserted into said vessel and it is driven until it reaches the vessel affected by stenosis. On said guidewire is then slidably mounted to an oblong inflatable element, conventionally called balloon in spite of its elongated shape, where one of said stent is crimped.

The inflatable element is driven to the affected area where it is inflated, thus assuming a larger diameter. The stent, whose diameter is initially smaller than that of the stenosis in order to be inserted inside it, expands, advanced by the inflatable element assuming a diameter nearly equal to that of the sound vessel.

Successively, the inflatable element is deflated and removed together with the guidewire; the stent instead remains positioned in correspondence of the area affected by stenosis. The plaques forming the stenosis are microcracked or held outside the vessel passageway and kept in that position by the stent itself.

Therefore, this angioplasty method allows the treatment of a wide range of vascular stenosis without the use of classic surgery. In this way, the patient is spared from too much suffering and its staying in the hospital is drastically reduced.

However, the delivery of the stent can be hindered by the specific conformation of the vessel affected by stenosis.

In particular, this kind of surgery is more difficult to perform in correspondence of stenosis located on vessels bifurcations, very common in coronary arteries, having a Y-shaped configuration with a proximal leg (near the specialist) and two distal legs (far from the specialist).

In this regard, many ways of implanting stents implying the insertion of two guidewires, one for each of the distal legs of the bifurcation, have been proposed.

One method implies the delivery, with a first element, of an enlarged mesh stent bridging the bifurcation inside the proximal leg and the distal leg. Then a second stent in the second distal leg with a second inflatable element is inserted through the enlarged meshes.

This method extends the time of the intervention and the first stent runs the risk of being damaged by the second. Furthermore, the second stent cannot branch out completely from the first but either it leaves a part of the vessel wall uncovered or it projects with its proximal end inside duct defined by of the first stent.

Another method, called of kissing balloons, consists in the delivery of two adjacent stents by inserting a pair of inflatable elements adhering the one to the other throughout their length, each one placed on a corresponding guidewire. Once they are delivered, the two stents provide a complete covering of the vessel walls, but create a longitudinal separation wall in the proximal leg of the bifurcation. Said separation wall hinders the blood flow and can be the cause of the formation of thrombosis and/or atherosclerotic plaques.

A third method consists in the delivery of different stents for each leg of the bifurcation. The delivery can also be performed either by mounting the three stents on a pair of kissing balloons or by mounting only the distal stents.

This method does not hinder the blood flow, but it does not cover the central part of the wall of the vessel bifurcation.

The technical problem at the roots of the present invention is that of providing a stent that overcomes the above mentioned drawbacks with reference to the already known methods of performing angioplasty.

The idea to solve such a problem consists in conferring to a stent the appropriate structural peculiarities to overcome the above mentioned problem, remaining in the field of the present angioplasty methods.

Said problem is solved by a stent as specified above, characterised in that it comprises a proximal side-branch, a first and a second distal side-branches, placed on a substantially Y-shaped configuration and each of them comprising said tubular segments in different queuing, and a linking segment among said side-branches having at least one wire-like element formed by extendible turns and laying on a two-lobe surface, said proximal side-branch and said first and second distal side-branches being fixed to the linking segment by connection elements.

The main advantage of the stent according to the present invention lies in the fact that it allows its delivery by the common method of kissing balloons and that it is structurally resistant as well as feasible to different shapes of bifurcations, without interfering with the vessel flow and without leaving the vessel walls uncovered.

The present invention will be described herebelow according to a present embodiment thereof, given as a non-limiting example. Reference will be made to the attached drawings, wherein:

* figure 1 shows a perspective view of the stent according to the present invention;
* figure 2 shows a perspective view of a detail of the stent of figure 1 and in a different angle-shot; and
* figures from 3 to 6 show the steps to deliver the stent of figure 1 in a vessel bifurcation affected by stenosis.

With reference in particular to figure 1, a stent is indicated 1. Said stent is intended to be delivered by percutaneous angioplasty in a coronary bifurcation B affected by stenosis caused for example by atherosclerotic plaque deposits P spread throughout the walls of the bifurcation B.

The stent 1 comprises a plurality of radially expandable tubular segments 2, that can plastically assume different diameters if they are enlarged or narrowed. The tubular segments 2 are placed in mutual queuing in the way described herebelow.

The stent 1 comprises a proximal side-branch 3, a first distal side-branch 4 and a second distal side-branch 5 placed in a substantially Y-

shaped configuration, similar to the bifurcation vessel B, and all comprising the tubular segments 2 in different queuing.

Each tubular segment 2 has a metallic wire-like element 6 and it is conformed in the successive extendible turns 7, that can therefore have their angular displacement varied if under stress.

In the present embodiment, each wire-like element 6 is conformed according to a closed sinusoid having the proximal apices 8 and the distal apices 9.

In each side-branch 3, 4, 5, the segments 2 are lined in a way as to place the proximal apices 8 between the two distal apices 9 and viceversa.

The substantially sinusoidal configuration allows the largest possible expandability of the tubular segment 2 with the slightest variation of its length.

Furthermore, each wire-like element 6 of the tubular segments 2 lays on a substantially cylindrical surface having an axis of symmetry. The axis of symmetry of the proximal side-branch, of the first distal side-branch and of the second distal side-branch are indicated respectively with H, J, K.

The adjacent tubular segments 2 are fixed therebetween by connection elements comprising a plurality of stems 10 fixed on the edges of the tubular segments 2 at respectively a proximal apex 8 and at a correspondent distal apex 9 of the successive tubular segment 2 on the maximum possible length between the apices 8, 9.

The stems 10 are fixed alternating a proximal apex 8 with the stem 10 and an apex 8 without the stem 10, to the respective distal apices 9.

Each stem 10 is substantially parallel to the axis of symmetry H, J or K of its side-branches 3, 4 or 5.

The stent 1 comprises a linking segment 11 between said side-branches 3, 4 and 5 having a wire-like element, similar to the previous ones and indicated with 6', which is as well conformed in successive extendible turns 7, in a closed sinusoid.

The wire-like element 6' lays on a two-lobe surface 12, 13, and on a substantially two-lobe transversal section. Therefore, the linking segment 11 comprises a first lobe 12, corresponding to the first distal side-branch 4 having substantially the same diameter, and a second lobe 13, corresponding to the second distal side-branch 5, having substantially the same diameter.

The side-branches 3, 4 and 5 are fixed to the linking segment 11 by the stems 10a-10d whose position will be detailed explained further below.

The lobes 12, 13 are substantially circular and divided by a separating region delimited in its upper and lower periphery by curved lines defining respective recesses 14. The recesses 14 are separated therebetween so that the linking segment 11 has an "8" configuration, opened in the centre.

The linking segment 11 has a proximal apex at both recesses 14.

The lobes 12, 13 have different axis of symmetry that are respectively coincident, and thus geometrically parallel, to the axis J, K of the distal side-branches 4, 5. This means that the respective transversal sections of lobes 12, 13 are not on a parallel plane, but create an angle substantially complementary to the angle comprised between the distal side-branches 4, 5.

In this way, the first and the second side-branches 4, 5 have at rest a prefixed angle α therebetween.

Each distal side-branch 4, 5 is fixed to the corresponding lobe 12, 13 of the linking segment 11 by a first linking stem 10a placed laterally and externally to the Y-shaped configuration.

A second linking stem 10b is placed at the top and a third linking stem 10c is placed at the bottom, both fixed to the proximal apex 8 adjacent to the recess 14.

The proximal side-branch 3 is fixed to the linking segment 11 by four stems 10d fixed respectively to the proximal apices 8 of the tubular segment 2, of the proximal side-branch 3, facing the linking segment 11, said proximal apices 8 being those laterally adjacent to the distal apices 9, of the same above mentioned tubular segment 2, facing at the recesses 14, comprising, as mentioned above, the proximal apices 8.

The disposition of the stems 10a-10d guarantees the smallest angular shift of said stems with respect to the segments 2, 11 to which they are fixed.

The prefixed angle α is comprised in a range between 0° and 50°, preferably between 20° and 40°.

According to a conventional method, the tubular segments 2, the stems 10 and the linking segment 11 can be machined from a stainless steel bar through laser cutting.

The surfaces of the stems 10 and of the wire-like elements 6, 6' can be conventionally gold-plated and have a substantially elliptical section

having diameters of 95 μm and 60 μm. The larger diameter is tangent to the cylindrical surface where the wire-like element 6 lays.

The proximal side-branch 3 has three tubular segments 2 in series each one having eight sinusoids 7; the distal side-branches 4, 5 have three tubular segments 2 in series each one having six sinusoids 7; the linking segment 11 has twelve sinusoids 7: five per lobe and two at the respective recesses 14.

However, it is implicit that the number of segments per side-branch and of sinusoids per segment can vary according to specific therapeutical requirements.

The particular shape of the linking segment 11 allows the distal side-branches 4, 5 to be firmly fixed to the proximal side-branch 3. Furthermore, the linking segment 11 allows a considerable angular deformation, particularly at the recesses 14 where the sinusoids 7 can be extended or narrowed depending on the different stages of angioplasty.

The delivery of the stent 1 will be described herebelow with reference to figures 3 to 6.

The stent 1 is appropriately crimped to a pair of inflatable oblong elements A, conventionally called balloons, placed as to coincide the one on the other throughout their length. Each distal side-branch 4, 5 contains just one inflatable element A while the proximal side-branch 3, having a larger diameter, contains both the inflatable elements A.

Each inflatable element A is slidably mounted to a guidewire G previously inserted inside the coronary bifurcation B. Each leg of the bifurcation B contains a different guidewire G.

The guidewires G and, successively, the inflatable elements A are introduced by percutaneous angioplasty through, for example, the femoral artery of the patient.

The inflatable elements A can be slidably advanced to the respective guidewire G. In their terminal part which supports the stent 1, the inflatable elements A contain the guidewire G.

For example, in case of coronary arteries, the proximal side-branch 3 is crimped to the inflatable elements A thus reaching the dimension of 1.8 mm in transversal outline, while each distal side-branch 4, 5 is crimped to the respective inflatable element A. Each one of them reaches the dimension of around 2 mm. At rest, and before being compressed and wrinkled to be

inserted in the kissing inflatable elements, the opening between the distal side-branches 4, 5 is of 30°.

The stent 1 is driven to the coronary bifurcation B affected by stenosis (figure 3) and conveniently placed (figure 4). In this regard, the stent 1 is made of slightly radiopaque material, to be seen in the best possible way while angioplasty is performed.

Once that the stent 1 has been positioned, the inflatable elements A are expanded, bringing the extension of the stent 1 up to a diameter of 3.5 mm for the distal side-branches 4, 5 and 4.5 mm for the proximal side-branch 3 (figure 5).

At this point, the inflatable elements A are deflated and removed together with the guidewires G.

After the removal of the inflatable elements A, the stent 1 adheres to the walls of the coronary bifurcation B and compresses the atherosclerotic plaques P substantially clearing the passageway in the bifurcation B and allowing a free flow of the blood (figure 6).

The above described stent 1 can be subject to modifications that are however comprised in the field of the present invention.

In particular, the side-branches can have a different conformation, and, for example, being formed by a single wire-like helicoidal element having a sinusoidal shape. In this way, the tubular segments would be represented by the helix coils while the same wire-like element would be the connecting element between the segments.

The distal side-branches can have different diameters and length and having, for example, an elliptic shape.

In the same way, the proximal side-branch and the single lobes can detach from the circular section.

Furthermore, the angle of inclination of the distal side-branches can be determined by the peculiar conformation of the connecting elements and by the mutual inclination of the lobes of the linking segment.

In order to avoid excessive cicatrization caused by the delivery of the stent, it is possible to cover the stent with a flexible covering, made, for example, out of autologous tissue coming from a blood vessel of the patient, or out of an appropriate tissue, like a tissue out of the pericardium of an animal.

Further to the above mentioned advantage, the above described stent allows a remarkable versatility of application as far as angioplasty is concerned, for angioplasty methods aimed at different forms of vascular narrowing such as atherosclerotic stenosis, restenosis and similar.

In order to satisfy particular requirements and contingencies, a person skilled in the art will be able to carry out numerous further modifications and variations to the endovascular stent described above, without departing thereby from the protective scope of the invention as defined by the following claims.

CLAIMS

1. A stent (1), used in particular in angioplasty, comprising a plurality of tubular segments (2) radially expandable and on mutual queuing, each one having at least one wire-like element (6) conformed in successive extensible turns (7) and laying on a substantially cylindrical surface, each tubular segment (2) being fixed to the tubular segments (2) adjacent by connection elements (10), characterised in that it comprises a proximal side-branch (3), a first distal side-branch (4) and a second distal side-branch (5), placed on a substantially Y-shaped configuration and each one of them comprising said tubular segments (2) in different queuing, and a linking segment (11) between said side-branches (3, 4, 5) having at least one wire-like element (6') conformed in successive extensible turns (7) and laying on a two-lobe surface (12, 13), said proximal side-branch (3) and said first and second distal side-branches (4, 5) being fixed to the linking segment (11) by connection elements (10a-10d).

2. The stent (1) according to claim 1, wherein the first and the second distal side-branches (4, 5) are fixed to the respective lobes (12, 13) of the linking segment (11) having at rest, before its use, a prefixed angle (α) therebetween.

3. The stent (1) according to claim 2, wherein said prefixed angle (α) is comprised in a range between 0° and 50°.

4. The stent (1) according to claim 3, wherein said prefixed angle (α) is comprised in a range between 20° and 40°.

5. The stent (1) according to any of the previous claims, wherein the lobes (12, 13) of the linking segment (11) present different axis of symmetry substantially parallel to the corresponding axis of symmetry (J, K) of the respective distal side-branches (4, 5).

6. The stent (1) according to any of the previous claims, wherein each lobe (12, 13) and the corresponding distal side-branches (4, 5) have substantially the same diameter.

7. The stent (1) according to any of the previous claims, wherein the lobes (12, 13) are separated by the recesses (14) opposite and separated therebetween.

8. The stent (1) according to claim 7, wherein each recess (14) has an extensible turn (7).

9. The stent (1) according to any of the previous claims, wherein the tubular segments (2) and the linking segment (11) comprise each one a wire-like element (6, 6') conformed in a closed sinusoid and having the proximal apices (8) and the distal apices (9).

10. The stent (1) according to claims 8 and 9, wherein each recess (14) has a proximal apex (8).

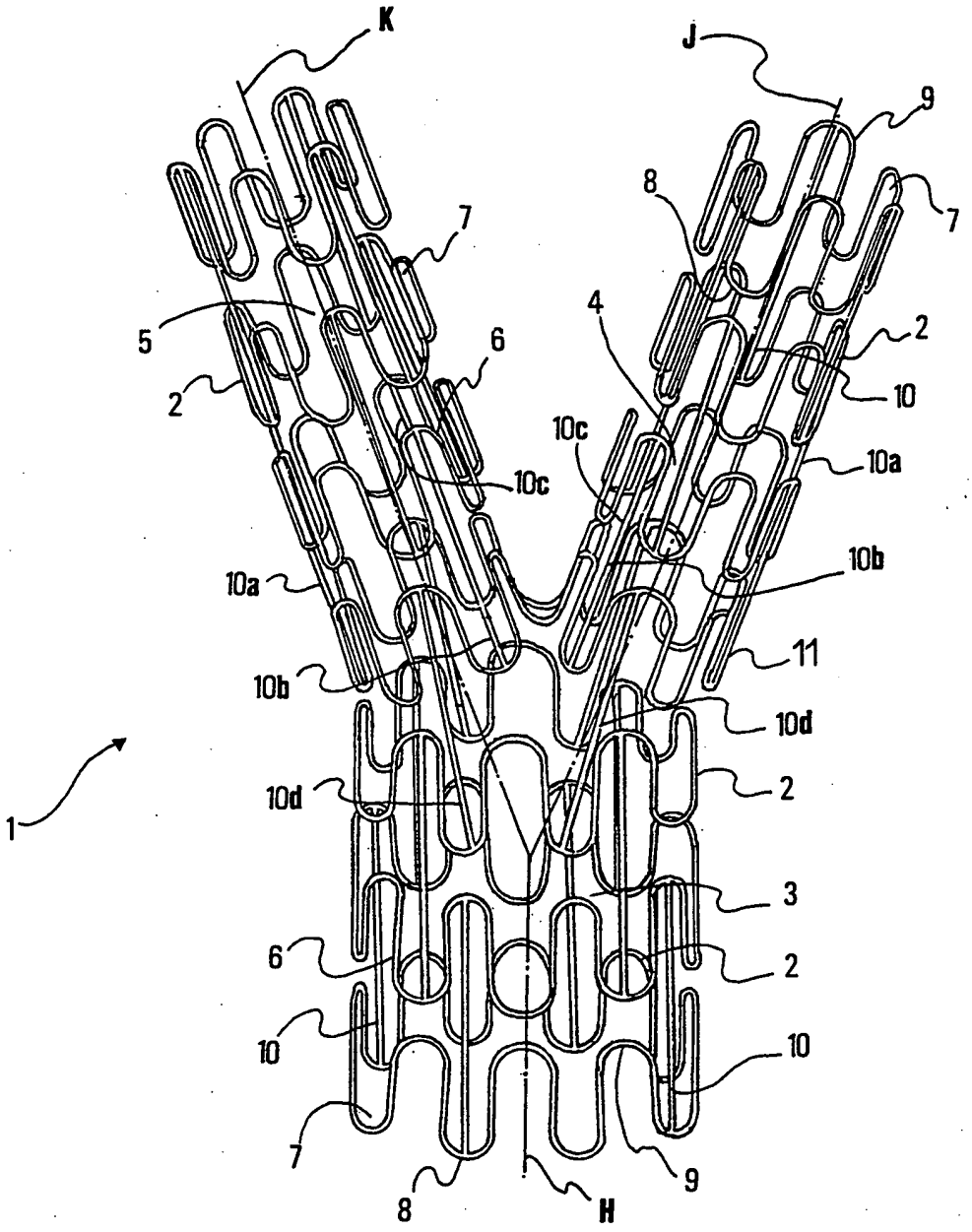
11. The stent (1) according to claim 9, wherein the connection elements comprise a plurality of stems (10) fixed to the tubular segments (2), each one extended between a proximal apex (8) of a tubular segment (2) and a corresponding distal apex (9) of the tubular segment (2) of the maximum length between said apices (8, 9), said stem (10) being substantially parallel to the axis of symmetry (H, J, K) of the corresponding side-branches (3, 4, 5).

12. The stent (1) according to claim 11, wherein the stems (10) are fixed alternating a proximal apex (8) with the stem (10) and a proximal apex (8) without stem (10), to the respective apices (9).

13. The stent (1) according to claim 11, wherein the side-branches (3, 4, 5) and the linking segment (11) are fixed therebetween by connection elements comprising a plurality of stems (10a, 10b, 10c, 10d).

14. The stent (1) according to claim 13, wherein each distal side-branch (4, 5) is fixed to the corresponding lobe (12, 13) by a first linking stem (10a) placed laterally and externally to the Y-shaped configuration, a second linking stem (10b) placed at the top and a third linking stem (10c) placed at the bottom, both said second and third linking stem (10b, 10c) being fixed to the proximal apex (8) of the linking segment (11) adjacent to the recess (14).

15. The stent (1) according to claim 13, wherein the proximal side-branch (3) is fixed to the linking segment (11) by four linking stems (10d) fixed respectively to the proximal apices (8) of the tubular segment (2), of the proximal side-branch (3), facing the linking segment (11), said proximal apices (8) being laterally adjacent to the distal apices (9) of same tubular segment (2), that are facing the recesses (14).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10c
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10d
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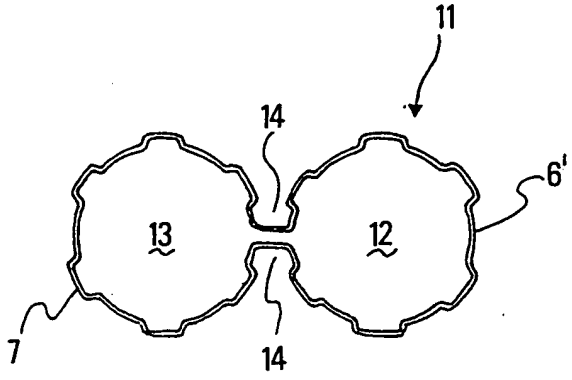
FIG 1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6'
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12
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14

FIG 2

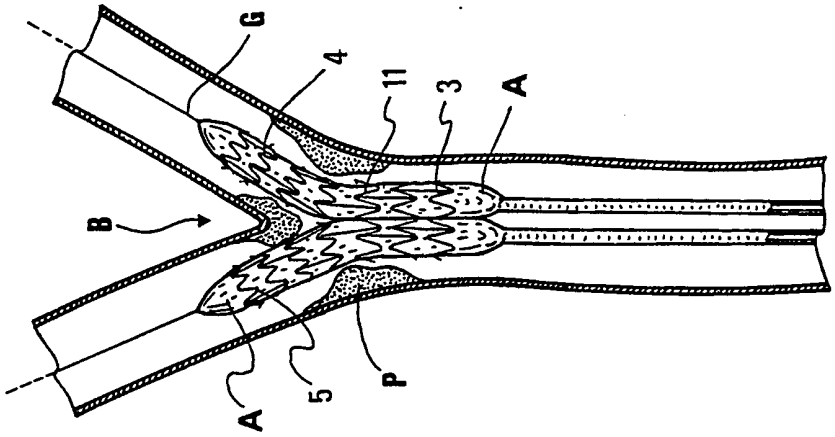

FIG 4

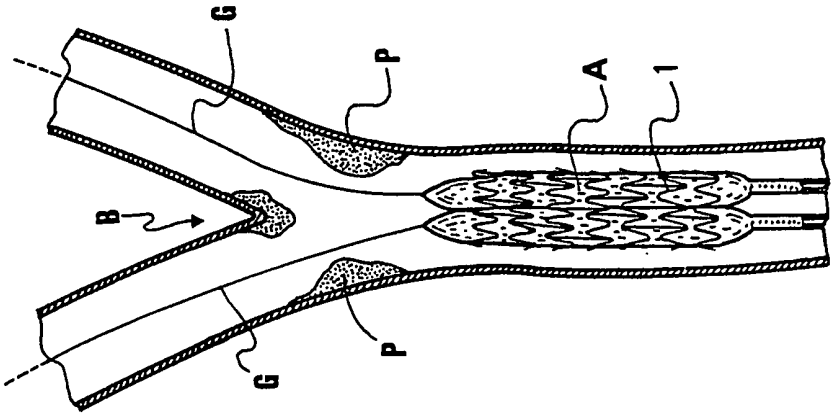

FIG 3

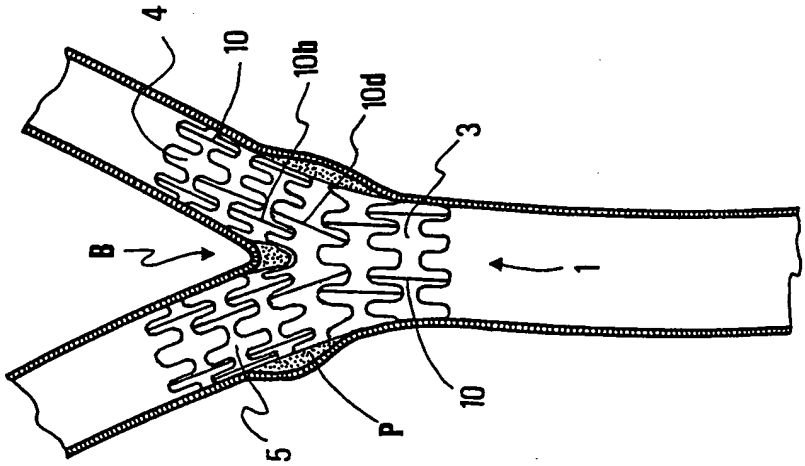

FIG 6

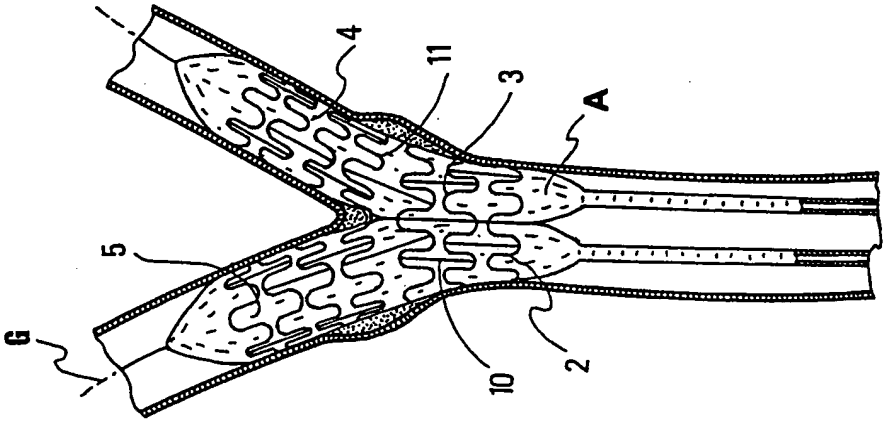

FIG 5

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/IT 98/00209

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 14028 A (DIVYSIO SOLUTIONS LTD.) 17 May 1996 see the whole document	1-10
A	WO 96 34580 A (DIBIE) 7 November 1996 see abstract; figures	1
A	US 4 994 071 A (MACGREGOR) 19 February 1991 see abstract; figures	1

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Date of the actual completion of the international search	Date of mailing of the international search report
3 November 1998	12/11/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, C

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte onal Application No
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